U.S. Serial No.: 10/667,151
Group Art Unit 1614
Examiner Charlesworth Rae

STATUS OF CLAIMS

Claims 1-39 are pending in this application, claims 1, 27 and 33 being the independent claims. Claims 22-37 have been withdrawn due to a restriction requirement by the Examiner, and therefore, claims 1-21, 38 and 39 are subject to examination.

REMARKS

Restriction Requirement

Applicant gratefully acknowledges the Examiner's statement that the species election requirement with respect to the chemical ablation agents and biodisintegrable viscosity adjusting agents, both in connection with the invention of Group I are considered persuasive.

Rejection regarding Non-statutory Obviousness-Type Double Patenting

Claims 1-21 and 38-39 are rejected provisionally under the judicially created doctrine of non-statutory obvious-type double patenting under 103(a) as being unpatentable over claim 40 in view of claims 1-39 of co-pending U.S. Patent Application No. 11/124,828 ('828).

In response, Applicants respectfully traverse the non-statutory obviousness-type double patenting rejection and its accompanying remarks. Applicants state that Applicants will submit a terminal disclaimer when the non-statutory obviousness-type double patenting rejection is the only rejection remaining in the application and the claims are otherwise deemed allowable by the Examiner. Until such time, Applicants respectfully request that this rejection be held in abeyance pending the disposition of the '828 application since the double patenting issue has not yet matured for rational argument (e.g., the co-pending application has not issued as a patent, the claims may be amended in the future, etc.).

Rejection under 35 U.S.C. 103(a)

Claims 1-13, 19-21, and 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gentz et al. (US Patent 6,869,927 B1, "Gentz"). Claims 14-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gentz in view of Flacke et al. (*Circulation*, 2001), and in view

of Glajch et al. (US Patent 5,147,631, "Glajch").

In response, Applicants respectfully traverse the rejections and their supporting remarks. Applicants state that the Examiner has not met his burden of establishing a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest ***all*** the claimed features. In addition, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in Applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Applicants state that Gentz et al., either in combination with the secondary references or alone, fails to teach ***all*** of the claimed elements of the present invention. The invention of claim 1, is directed to an injectable formulation comprising: (a) a ***chemical ablation agent in an amount effective to cause tissue necrosis***, and (b) a biodisintegrable viscosity adjusting agent in an amount effective to render the formulation highly viscous, wherein said injectable formulation is a sterile injectable formulation.

Gentz et al. does not teach a chemical ablation agent in an amount effective to cause tissue necrosis, as claimed. Rather, Applicants states that Gentz et al. discloses "formulations of KGF-2 polypeptides ***to promote or accelerate soft tissue growth or regeneration, for example in wound healing***" (col. 2, lines 14-16)(emphasis added) and such formulations can include "NaCl, glycine, sucrose or mannitol, or combinations thereof, as a tonicifier at a concentration of from about 0mM to about 150 mM." (col. 4, lines 33-36). Gentz et al. does not even remotely teach or suggest a chemical ablation agent for effecting tissue necrosis. Indeed, the words "chemical ablation," "ablation agent," or necrosis do not appear anywhere in the reference. The Examiner has not offered any evidence to support the argument that Gentz et al. discloses a "chemical ablation agent in an amount effective to cause tissue necrosis." Such assumption,

however, would be contrary to the basic teaching of Gentz et al., which discloses formulations for "soft-tissue growth and regeneration." (col. 2, lines 2-3).

Instead of offering evidence, the Examiner states that "sodium chloride of about 150 mM is reasonably construed to serve as a chemical ablation agent in [an] amount effective to cause tissue necrosis and to reasonably serve as a biodisintegrable viscosity adjusting agent in an amount effective to render the formulation highly viscous." Even if it were assumed that sodium chloride of about 150 mM is of sufficient concentration to cause tissue necrosis, Applicants respectfully state that the formulations of Gentz et al. themselves are not 150nM NaCl, but rather, are "isotonic." For example, although several of the examples disclose using "125 nM NaCl," as one of the ingredients in the formulations, it is clear upon close inspection that the NaCl is then diluted with other components. For instance, Gentz et al. discloses that "the lyophilized KGF-2 polypeptide formulations are reconstituted in sterile water so as to maintain ***isotonic*** conditions of about 290 mOsm." (col. 7, lines 47-61). Another example teaches taking 125 nM NaCl, and mixing it with other components, including "water as diluent." (col. 6, line 19).

As would be appreciated by one of ordinary skill in the art, an ***isotonic*** NaCl solution would ***not*** cause tissue necrosis. Thus, Gentz et al. fails to teach or suggest the claimed ***chemical ablation agent in an amount effective to cause tissue necrosis***.

In addition, given that Gentz et al. is directed to formulations for soft-tissue healing, Applicants state that one of ordinary skill in the art would have no motivation to modify the formulations of Gentz et al. to arrive at the claimed invention. Rather, one of ordinary skill would be dissuaded from using such formulations to necrotize soft-tissue given the teachings of Gentz et al. Even if it were assumed that such motivation were to exist, the combined references fail to teach or suggest all of the claimed features.

The secondary references fail to remedy this deficiency. Neither Flacke or Glajch teaches a chemical ablation agent in an amount effective to cause tissue necrosis. Flacke was cited for purportedly teaching MRI contrast agents and Glajch was cited for purportedly teaching ultrasound contrast agents. Neither reference teaches or mentions any of the elements of

independent claim 1. As such, they do not help remove the basic infirmity of the primary reference in establishing a *prima facie* case of obviousness.

For at least these reasons, Applicants respectfully submit that claims 1-21 and 38-39 are patentable over the cited references.

CONCLUSION

Applicants submit Claims 1-39 are in condition for allowance, early notification of which is earnestly solicited. Should the Examiner be of the view that an interview would expedite consideration of this Amendment or of the application at large, request is made that the Examiner telephone the Applicants' attorney at (908) 518-7700 in order that any outstanding issues be resolved.

FEES

The Examiner is authorized to charge the petition fee for a three-month extension of time and any other fees deemed to be owing for this application to Deposit Account Number 50-1047.

Respectfully submitted,

Keum J. Park
Registration No. 42,059

Attorney for Applicant
Mayer & Williams PC
251 North Avenue West, 2nd Floor
Westfield, NJ 07090
(908) 518-7700 Tel.
(908) 518-7795 Fax